



Handbook for Providers of Laboratory Services

Chapter L-200 Policy and Procedures for Laboratory Services

Illinois Department of Healthcare and Family Services
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Chapter L-200

Laboratory Services

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Foreword

Purpose

This handbook has been prepared for the information and guidance of providers who provide laboratory services for participants in the Department's Medical Programs. It also provides information on the Department's requirements for provider participation and enrollment.

This [handbook](#) can be viewed on the Department's website.

This handbook provides information regarding specific policies and procedures relating to laboratory services. It is important that both the provider of service and the provider's billing personnel read all materials prior to initiating services to ensure a thorough understanding of the Department's Medical Programs policy and billing procedures. Revisions in and supplements to the handbook will be released from time to time as operating experience and state or federal regulations require policy and procedure changes in the Department's Medical Programs. The updates will be posted to the Department's website at

<http://www.hfs.illinois.gov/releases/>

Providers will be held responsible for compliance with all policy and procedures contained herein.

Inquiries regarding coverage of a particular service or billing issues may be directed to the Bureau of Comprehensive Health Services at 877-782-5565.

Chapter L-200

Laboratory Services

L-200 Basic Provisions

For consideration to be given by the Department for payment of laboratory services, such services must be provided by a provider enrolled for participation in the Department's Medical Programs. Services provided must be in full compliance with both the general provisions contained in the Handbook for Providers of Medical Services, General Policy and Procedures (Chapter 100) and the policy and procedures contained in this handbook. Exclusions and limitations are identified in specific topics contained herein.

L-201 Provider Participation

An independent laboratory is one that is independent both of the attending or consulting physician and of a hospital.

Participation requirements for medical providers that do not meet the definition of an independent laboratory, but are providing laboratory services in their own offices or in a hospital, can be found in Chapter 200 for the specific provider type.

CLIA requirements described in topic L-201.5 apply regardless of provider type.

L-201.1 Participation Requirements

An independent laboratory holding a valid license issued by the Illinois Department of Public Health (or meeting the requirements of the state in which the laboratory is located), a valid current Clinical Laboratory Improvement Act (CLIA) Certificate and a certification by the Social Security Administration for participation in the Medicare Program (Title XVIII) is eligible to be considered for enrollment to participate in the Department's Medical Programs.

Procedure: The provider must complete and submit:

- Form HFS 2243 (Provider Enrollment/Application)
- Form HFS 1413 (Agreement for Participation)
- HCFA 1513 (Disclosure of ownership and controlling interest)
- W9 (Request for Taxpayer Identification Number)

These forms may be obtained from the Provider Participation Unit. E-mail requests for enrollment forms should be addressed to:

hfs.ppu@illinois.gov

Providers may also call the unit at (217)782-0538 or mail a request to:

Illinois Department of Healthcare and Family Services
Provider Participation Unit
Post Office Box 19114
Springfield, Illinois 62794-9114

The forms must be completed (**printed** in ink or typewritten), signed and dated in ink by the provider, and returned to the above address. The provider should retain

a copy of the forms. The date on the application will be the effective date of enrollment unless the provider requests a specific enrollment date and it is approved by the Department.

A copy of the CLIA certificate in the name and address of the provider requesting enrollment must accompany the enrollment forms. Refer to Topic 201.5 for detailed CLIA information.

Participation approval is not transferable - When there is a change in ownership, location, laboratory name, or a change in the Federal Employer's Identification Number, a new application for participation must be completed. The application should be accompanied by a copy of the letter from the Laboratory Regulation and Certification Unit, of the Department of Public Health, verifying the change of the CLIA certificate. Claims submitted by the new owner using the prior owner's assigned provider number may result in recoupment of payments and other sanctions.

L-201.2 Participation Approval

When participation is approved, the provider will receive a computer-generated notification, the Provider Information Sheet, listing all data on the Department's computer files. The provider is to review this information for accuracy immediately upon receipt. For an explanation of the entries on the form, see Appendix L-2.

If all information is correct, the provider is to retain the Provider Information Sheet for subsequent use in completing claims (billing statements) to ensure that all identifying information required is an exact match to that in the Department files. If any of the information is incorrect, refer to Topic L-201.4.

L-201.3 Participation Denial

When participation is denied, the provider will receive written notification of the reason for denial.

Within ten calendar days after this notice, the provider may request a hearing. The request must be in writing and must contain a brief statement of the basis upon which the Department's action is being challenged. If such a request is not received within ten calendar days, or is received, but later withdrawn, the Department's decision shall be a final and binding administrative determination. Department rules concerning the basis for denial of participation are set out in 89 Ill. Adm. Code 140.14. Department rules concerning the administrative hearing process are set out in 89 Ill. Adm. Code 104 Subpart C.

L-201.4 Provider File Maintenance

The information carried in the Department's files for participating providers must be maintained on a current basis. The provider and the Department share responsibility for keeping the file updated.

Provider Responsibility

The information contained on the Provider Information Sheet is the same as in the Department's files. Each time the provider receives a Provider Information Sheet, it is to be reviewed carefully for accuracy. The Provider Information Sheet contains information to be used by the provider in the preparation of claims; any inaccuracies found are to be corrected and the Department notified immediately.

Any time the provider effects a change that causes information on the Provider Information Sheet to become invalid, the Department is to be notified. When possible, notification should be made in advance of a change.

Procedure: The provider is to line out the incorrect or changed data, enter the correct data, sign and date the Provider Information Sheet with an original signature on the line provided. Forward the corrected Provider Information Sheet to:

Illinois Department of Healthcare and Family Services
Provider Participation Unit
Post Office Box 19114
Springfield, Illinois 62794-9114

Failure of a provider to properly notify the Department of corrections or changes may cause an interruption in participation and payments.

Department Responsibility

When there is a change in a provider's enrollment status or a change is submitted by the provider, the Department will generate an updated Provider Information Sheet reflecting the change and the effective date of the change. The updated sheet will be sent to the provider and to any payees listed if the address is different from the provider.

L-201.5 Clinical Laboratory Improvement Amendments (CLIA) Certification

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, apply to laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of, the health of human beings. No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a CLIA certificate issued by the Department of Health and Human Services that is applicable to the specialty or subspecialties of laboratory services offered by the provider. The provider may obtain one of four types of CLIA certificates:

- A. Certificate of Waiver
- B. Physician Performed Microscopic Procedure
- C. Certificate of Accreditation
- D. Certificate of Compliance

To receive reimbursement for laboratory services, all providers, regardless of type of business or professional licensure, must have a current CLIA certificate on file with the Department. Payment will not be made for laboratory services performed by a provider if the Department does not have the required CLIA certification as described below.

- A CLIA certificate issued to an independent laboratory is effective only for that laboratory and no other entity. A physician or hospital cannot submit the CLIA certification of an independent laboratory and attempt to bill the Department for laboratory services using that certification.
- The certificate must be issued in the specific name and address of the enrolled provider who will be billing for the laboratory services. Exceptions to this are:
 - A clinic may enroll with the Department as an independent laboratory or may place its CLIA certificate in each of the clinic's physician files. However, the clinic cannot do both.
 - A pathologist contracted by a hospital may submit a CLIA certificate for the contracting hospital.

For additional information on the CLIA certification process please contact:

Illinois Department of Public Health
Laboratory Regulation
525 West Jefferson Street
Springfield, IL 62761
(217) 782-7412

L-202 Laboratory Reimbursement

Many laboratory tests have both a technical and professional component. Refer to Topic L-210 for an explanation of the circumstances under which each is billed to the Department.

L-202.1 Charges

Charges billed to the Department must be the provider's usual and customary charge billed to the general public for the same service or item. Providers may only bill the Department **after** the service or item has been provided.

A provider may only charge for services he or she personally provides. Providers may not charge for services provided by another provider, even though one may be in the employ of the other.

Charges for services and items provided to participants enrolled in a Managed Care Organization (MCO) must be billed to the MCO according to the contractual agreement with the MCO.

L-202.2 Electronic Claims Submittal

Any services which do not require attachments or accompanying documentation may be billed electronically. Further information concerning electronic claims submittal can be found in the Chapter 100, Topic 112.3.

Providers billing electronically should take special note of the requirement that Form HFS 194-M-C, Billing Certification Form, must be signed and retained for a period of three years. Failure to do so may result in revocation of the provider's right to bill electronically, recovery of monies or other adverse actions. Form HFS 194-M-C can be found on the last page of each Remittance Advice which reports the disposition of any electronic claims. Refer to Chapter 100, Topic 130.5 for further details.

Please note that the specifications for electronic claims billing are not the same as those for paper claims. Please follow the instructions for the medium being used. If a problem occurs with electronic billing, providers should contact the Department in the same manner as would be applicable to a paper claim. It may be necessary for providers to contact their software vendor if the Department determines that the service rejections are being caused by the submission of incorrect or invalid data.

L-202.3 CLAIM PREPARATION AND SUBMITTAL

Refer to Chapter 100, Topic 112, for general policy and procedures regarding claim submittal. For general information on billing for Medicare covered services and submittal of claims for participants eligible for Medicare Part B, refer to Chapter 100, Topics 112.5 and 120.1. For specific instructions for preparing claims for Medicare covered services, refer to Appendix L-1b.

The Department uses a claim imaging system for scanning paper claims. The imaging system allows more efficient processing of paper claims and also allows attachments to be scanned. Refer to Appendix L-1 for technical guidelines to assist in preparing paper claims for processing. The Department offers a claim scannability/imaging evaluation. Please send sample claims with a request for evaluation to the following address.

Illinois Department of Healthcare and Family Services
201 South Grand Avenue East
Second Floor - Data Preparation Unit
Springfield, Illinois 62763-0001
Attention: Vendor/Scanner Liaison

L-202.31 Preparation of Claims - Independent Laboratories

Form HFS 2211 (Laboratory/Portable X-Ray Invoice) is to be used by independent laboratories to submit charges for covered services. A copy of Form HFS 2211 and detailed instructions for its completion are included in Appendices L-1 and L-1a. The Physicians' Current Procedural Terminology (CPT) or HCFA Common Procedure Coding System (HCPCS) codes must be used when billing for test procedures.

L-202.32 Preparation of Claims - Other Providers

Form HFS 2360 (Health Insurance Claim Form) is to be used by all providers except independent laboratories to submit charges for covered services. Refer to the Handbook for Physicians, Chapter A-200, Appendix A-1 for detailed instructions on completing Form HFS 2360. The Physicians' Current Procedural Terminology (CPT) or HCFA Common Procedure Coding System (HCPCS) codes must be used when billing for test procedures.

L-202.33 Claims Submittal

All routine paper claims are to be submitted in a pre-addressed mailing envelope provided by the Department for this purpose, Form HFS 2245, Laboratory/Portable X-Ray Invoice Envelope. Use of the pre-addressed envelope should ensure that

billing statements arrive in their original condition and are properly routed for processing.

For a non-routine claim, use Form HFS 2248, NIPS Special Handling Envelope. A non-routine claim is:

- Any claim to which Form HFS 1411, Temporary MediPlan Card, is attached.
- Any claim to which any other document is attached.

For electronic claims submittal, refer to Topic L-202.2 above. Non-routine claims may not be electronically submitted.

L-202.4 Payment

Payment made by the Department for allowable services will be made at the lower of the provider's usual and customary charge or the maximum rate as established by the Department. Refer to Chapter 100, Topics 130 and 132, for payment procedures utilized by the Department and General Appendix 8 for explanations of Remittance Advice detail provided to providers.

Payment for allowable laboratory services includes collection and handling of specimens by laboratory personnel; use of laboratory equipment and supplies and the written report of test results to the referring practitioner.

Payment will not be made to a practitioner or a hospital for services performed at an independent laboratory.

L-202.5 Fee Schedule

The Department's maximum reimbursement rates for the allowable procedures are listed on the Department's website. The listing can be found at

<http://www.hfs.illinois.gov/reimbursement/>

Paper copies of the listings can be obtained by sending a written request to:

Illinois Department of Healthcare and Family Services
Bureau of Comprehensive Health Services
201 South Grand Avenue East
Springfield, IL 62763-0001

The maximum rates, quantity limitation and prior approval requirements for each

item are also available electronically. The Department maintains a downloadable rate file suitable for use in updating a provider's computerized billing system. This file is located in the same area on the Department's website as the listings described above. A copy of this file can also be obtained by sending a blank 3.5 inch IBM PC compatible diskette, a written request and a self-addressed, prepaid diskette mailer to the address listed above.

The website listings and the downloadable rate file are updated annually. Providers will be advised of major changes via a written notice. Provider notices will not be mailed for minor updates such as error corrections or the addition of newly created HCPCS codes.

L-203 Covered Services

A covered service is a service for which payment can be made by the Department. Refer to Chapter 100, Topic 103, for a general list of covered services. Payment for services will be made only when the following conditions have been met:

- The test for which charges are made is within the specialties or subspecialties the laboratory is CLIA certified by Medicare to provide, and
- The patient's referring practitioner has provided the laboratory with a written order for the test(s). (Refer to Topic L-205 for a description of acceptable documentation.)

Services and materials are covered only when provided in accordance with the limitations and requirements described in the individual topics within this handbook.

L-204 NON-COVERED SERVICES

Services for which medical necessity is not clearly established are not covered by the Department's Medical Programs. Refer to Chapter 100, Topic 104, for a general list of non-covered services.

In addition, the following laboratory services are excluded from coverage in the Department's Medical Programs and payment will not be made for the provision of these services:

- Laboratory services when not specifically required by the condition for which the patient is being treated such as blanket "rule out" or open-ended tests.
- Laboratory services provided to patients eligible for Medicare Part B benefits when the Medicare intermediary determines that the services are not medically necessary.
- Laboratory tests which are available without charge from other sources including, but not limited to, private and governmental agencies.
- Non-emergency blood lead tests performed by laboratories other than the Illinois Department of Public Health, unless the results are reported to the Illinois Department of Public Health. Refer to L-212.5
- Tests and study of specimens as a result of an autopsy examination.
- Tests which have not been performed on the laboratory's premises, by the laboratory's staff, using the laboratory's equipment and supplies.
- The collection and handling of specimens obtained for referral to another laboratory.
- Sensitivity studies when a culture shows no growth or when a growth is identified as beta hemolytic streptococcus.
- Culture identification procedures.

L-205 Record Requirements

The Department regards the maintenance of adequate records as essential for the delivery of quality medical care. In addition, providers should be aware that medical records are key documents for post-payment audits. Refer to Chapter 100, Topic 110 for record requirements applicable to all providers.

Additionally, Illinois laboratories must comply with State regulations governing the maintenance of medical records, as issued by the Illinois Department of Public Health (IDPH) and contained in IDPH's "Rules and Regulations for Clinical Laboratories and Blood Banks". Out-of-state laboratories must comply with applicable regulations in their state.

The basic records which must be retained include:

- All written orders from practitioners for laboratory services for Medical Assistance and All Kids participants. The written documentation may include, but not be limited to:
 - an original order
 - a copy of an original order faxed from the ordering practitioner's office
 - an electronic order e-mailed from the ordering practitioner's office
 - The order, regardless of medium, must clearly identify its source, including the name of the ordering practitioner. It must also include the exact test(s) to be performed (amount, frequency, and duration) and the diagnosis or condition of the patient pertinent to the order.
- Copies of all reports to referring practitioners.
- A method of verification of usual and customary charges to the general public.
- For non-emergency blood lead tests performed, documentation showing that the results were reported to the Illinois Department of Public Health.

The practitioner's written or electronic order must be contained in the laboratory's medical records. It must specify the test(s) ordered. The order must contain the patient's diagnosis or presenting symptoms which indicate the need for the specific test(s) ordered. The practitioner's state license number must be available to each lab to which referrals are made.

In the absence of proper and complete medical records, no payment will be made and payments previously made will be recouped. Lack of records or falsification of records may also be cause for a referral to the appropriate law enforcement agency for further action.

L-210 General Limitations and Considerations on Covered Services

L-210.1 Technical and Professional Components

For any given lab test, no more than one provider may be reimbursed for the technical component of a service and no more than one provider may be reimbursed for the professional component.

L-210.11 HFS 2211 Claim Form

Payment to an independent laboratory includes both the technical and professional components. Payment will not be made to a practitioner for the interpretation of any tests performed and billed by an independent laboratory.

- = Independent laboratories may not bill the Department for lab tests done during an inpatient stay. The all inclusive rate that the hospital receives is considered to cover all services provided during the inpatient stay.

L-210.12 HFS 2360 Claim Form

Providers using the HFS 2360 claim form to bill for laboratory services may be paid for the technical component, the professional component or the global service (technical and professional). The Place of Service Code, which is entered in Field 24 B on the claim, determines which component(s) are to be paid. In addition, hospitals billing fee-for-service must use a modifier (in the MOD Box) when the Place Code is E (Emergency Room). Modifier T denotes "Technical" only and P denotes "Complete" (both Technical and Professional components).

Hospitals may bill fee-for-service for lab tests performed in the Outpatient Department or the Emergency Room. For the Outpatient Department, if the tests are interpreted by a salaried physician, Place Code 3 or 11 (Office) is to be used and the Global fee will be paid. If interpreted by a non-salaried physician, Place Code 2 or 22 (Outpatient) is to be used and the Technical fee paid. For the Emergency Room, Place Code E with Modifier P must be used for the Global and Place Code E with Modifier T for the Technical only fee. Hospitals should not bill fee-for-service for the Professional Component only. Hospitals should not bill fee-for-service for any lab tests done for in-patients.

- = When the hospital bills only for the Technical Component, the non-salaried physician may bill for the interpretation (Professional Component). Physicians use Place Codes C (Outpatient Hospital) or E (Emergency Room) and NO modifiers to bill for the interpretation. Physicians may not bill for the technical component only.

Pathologists may bill for the Professional Component for lab tests done for in-patients as long as the pathologist is not salaried by the hospital. Place Code 1 or 21 is used for the interpretation.

Federally Qualified Health Clinics (FQHC), clinics and physicians who have laboratories in their offices may bill for the Global service when the tests are performed by their own laboratory. Place Code 3 or 11 is to be used to denote the Global service. These providers may not bill for laboratory tests collected and sent to another laboratory. In addition, payment will not be made to a second physician for interpretation of the same test(s).

L-210.2 Multiples of the Same Test on the Same Day

L-210.21 Independent Laboratories

In order for an independent laboratory to bill for multiples of the same test performed on the same date of service, the laboratory must use both the CPT code for the test being performed and the appropriate unlisted code. The CPT code for the test being performed is placed in the procedure code portion of the service section for test #1 and the name of the test or a description is placed in the procedure description field. The charge for the first test is placed in the provider charge field. The appropriate unlisted procedure (example 87999) is placed in the procedure code field of the next service section. The name(s) and number of the additional test(s) must be shown in the procedure description field and one charge, which includes all the additional tests billed under the unlisted code, is to be entered in the charge field. If there is not adequate space on the billing form to describe the additional service(s), either a narrative description of the test(s) or test results must be attached to the claim.

L-210.22 Hematology Tests for All Other Providers

A practitioner may bill for multiples of hematology services by using the days/unit field. When multiples of a hematology service are performed, the practitioner enters a 4 digit code in the days/unit field (example: 0004 for 4 tests within a 24 hour time period). If a quantity greater than 5 is placed in the Days/Units field, either the test results or a narrative explanation of the services must be attached to the claim.

A hospital billing fee for service for multiple hematology services is to use the same procedure as that described for a practitioner.

L-210.23 Pathology Services for All Other Providers

A practitioner may bill for multiples of pathology services by using the Days/Units field. When multiples of a pathology service are performed, the practitioner enters a 4 digit code in the Days/Units field (example: 0004 for 4 tests within a 24 hour time period). If a quantity greater than 5 is placed in the Days/Units field, either the test results or a narrative explanation of the services must be attached to the claim.

Certain laboratory tests which are not reasonably performed more than once on the same service date, for the same participant, are limited to a quantity of one, e.g., Pap Smears, DNA testing. If more than one of these services is repeated on the same day, the unlisted code is to be shown for the additional test(s) and tests results attached to the claim.

A hospital billing fee for service for multiple pathology services is to use the same procedure as that described for a practitioner.

L-212 Limitations and Considerations on Specific Services

L-212.1 Vitamin B12 Testing

Payment is allowable for Vitamin B12 and Folic Acid testing only when the possibility of macrocytic anemia is detected by a complete blood count (CBC). CBC test results performed within the past 30 days must be attached to the claim when charges are submitted for Vitamin B12 or Folic Acid testing.

L-212.2 Multiphasic Tests

Routine, multi phasic (battery) tests are covered only in those instances where the tests performed are consistent with the patient's diagnosis or condition.

L-212.3 Organ or Disease Oriented Panels

Appropriate CPT or Level II or III HCPCS codes for specific panels are to be used in lieu of individual codes to report organ panels or profiles that combine tests under a problem oriented classification. Organ or Disease Oriented Panel codes should be used only when all of the tests listed in the panel definition are performed. When all of the tests listed are not performed, individual test codes are to be used and a separate charge shown for each code. Individual codes are also to be used for automated tests that are not included in a panel code.

Providers may not submit charges for individual or profile codes for tests included in the panel(s) billed, and vice versa.

L-212.4 Therapeutic Drug Monitoring

Measurement of one or more drugs in body fluids or excreta may be billed under the specific procedure code for the drug(s) test. If no specific drug code exists, the unlisted Drug Assay code is to be used. When the unlisted code is used, the specific drug(s) tested for must be entered in the description field of the invoice. A copy of the test reports or a narrative listing of the drug(s) included in the charge must be attached. The unlisted code can only be used once for the same date, same patient, with one charge that includes all drugs which have no specific code.

L-212.5 Blood Lead Draws

Payment will be made to a laboratory for a "draw fee" if the laboratory obtains a specimen for delivery to a public health lab for a blood lead test. For non-emergency blood lead tests, the results must be reported to the Illinois Department of Public Health.

L-270 Home and Long Term Care Facility Services

Payment for travel to a patient's place of residence will be allowed only when:

- the patient's attending physician indicates on the order that the patient is physically unable to travel to a laboratory, and
- it is the custom of the laboratory to charge the general public a travel fee in addition to the fee for the laboratory service.

If the laboratory travels to the patient's place of residence, the laboratory should bill procedure code P9604 for travel.